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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/667,237 | 09/22/2000 | Stephen J. Reinl | 34150/0013 | 1339 |

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| EXAMINER |
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SHIBUYA, MARK LANCE

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| ART UNIT | PAPER NUMBER |
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1639

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|-------------------------------------|--|
| Office Action Summary | Application No. 09/667,237 | Applicant(s) REINL ET AL. | |
| | Examiner Mark L. Shibuya, Ph.D., | Art Unit 1639 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49 and 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49, 50 is/are rejected.
- 7) ☒ Claim(s) 50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 49 and 50 are pending and examined.

The Status of the Claims

2. The after final claim amendments, filed 5/22/2006, in the response to the Final rejection, mailed 2/22/2006, are **entered**. These amendments cancel all claims, except for claims 49 and 50. These amendments amend claim 49, to recite a sequence identifier (i.e., "SEQ ID:52"). The examiner has entered the claim amendments after final rejection in the interests of compact prosecution, especially in view of the notice to comply with the sequence rules, sent after Final rejection, mailed 2/22/2006.

Nucleotide/Amino Acid Sequences

3. Applicant's amendment, entered 8/25/2006, to the Sequence listing, (both paper and computer readable form) to bring the applicant into compliance with the sequence rules (see, 37 CFR 1.821-1.825), is acknowledged. The instant amendment to the Sequence Listing was required in the Office communication, mailed 6/16/2006, following applicant's after final amendments and remarks, filed 5/22/2006.

Procedural Posture of the Application

4. The instant claims are finally rejected. The instant Office action restarts the period for response. The rejection of claim 49, drawn to a product, for obviousness-type

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double patenting is extended to claim 50, drawn to a method for making the product of claim 49.

5. The final Office action, mailed 2/22/2006, indicated that claims 49 and 50 were allowable; which was an inadvertent mistake, because the rejection of claims 49 and 50 under non-statutory, obviousness-type double patenting, was and is maintained (see below rejection). However, claim 49 remains free of the prior art.

Election/Restrictions

6. The final Office action, mailed 2/22/2006, indicated that claim 50, drawn to making the library of claim 49, was rejoined to the invention that includes claim 49.

Withdrawn Claim Rejections

7. The following rejections are withdrawn in view of applicant's arguments and amendments to the claims.

8. Claims 1-4 and 9-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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9. Claims 1-4, 9, 12, 13 and 49 are rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cwirla et al., Proc. Natl. Acad. Sci. USA, vol. 87, pp. 6378-6382, August 1990.

10. Claims 1-4, 9, 12, 13 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holliger et al., U.S. 5,837,242, Keck et al., US 6,040,431, and Dower et al., WO 91/19818.

11. Claims 10, 11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holliger et al., U.S. 5,837,242, Keck et al., US 6,040,431, and Dower et al., WO 91/19818, as applied to claims 1-4, 9, 12, 13 and 49 above, and Turpen et al., WO 96/12028 (IDS filed 6/25/2002).

12. Claims 10, 11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cwirla et al., Proc. Natl. Acad. Sci. USA, vol. 87, pp. 6378-6382, August 1990, as applied to claims 1-4, 9, 12, 13 and 49 above, and Turpen et al., WO 96/12028 (IDS filed 6/25/2002).

Priority

13. This application, filed 9/22/2000, claims benefit of US Provision 60/155,978, filed 9/24/1999.

Claim Objections

14. Claim 50 is objected to because of the following informalities: A semicolon at the end of step d appears to have been mistakenly typed as a period. Appropriate correction is required.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 49 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54, 56, 60-64, 66, 67, 69, 72, 73, 76-86 of copending Application No. 09/539,382, (filed 3/31/2000).

This rejection maintains the reasons of record as set forth in the previous Office final action. This rejection is necessitated by the rejoining of claim 50. This rejoining is taken as an amendment to the claims. The rejection is copied below for the convenience of the reader.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because library of dual-domain nucleic acid molecules, each of which has a first and a second domain, said domains separated and linked by a linker, wherein said linker is a member of a randomized library of linkers, wherein the linkers of the library of linkers vary in size and nucleotide sequence and consist of a "repeated pattern of degenerate repeated triplet nucleotide", and variations thereof, and nucleic acid molecules thereof, **are made obvious by**, as the species anticipates or makes obvious the genus, a polynucleotide comprising a nucleic acid sequence encoding a polypeptide epitope of a B-cell lymphoma surface immunoglobulin antigen, wherein the polypeptide is a two domain single-chain antibody that includes at least part of the VH and VL domains (claim 64), where the domains are linked by an amino acid linker (claim 66), and where the linker is a member of a randomized library of linkers that vary in size and sequence, said library being encoded by nucleic acid sequences consisting of a repeated pattern of degenerate repeated triplet nucleotides, (claim 67), and variations thereof, as claimed in copending Application No. 09/539,382.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. This rejection maintains the reasons of record as set forth in the previous Office action.

Response to Arguments, mailed 2/22/2006

Applicant states their willingness to file a terminal disclaimer in either the instant case or in Application No. 09/539,382, depending on which case is granted first. Therefore, the instant provisional rejection is maintained.

The rejection of claim 50 for non-statutory obviousness-type double patenting rejection is necessitated by the rejoining of claim 50. Claim 50 is considered to be obvious because claim 50 is drawn to making the product of claim 49, which is obvious over Application No. 09/539,382, as set forth above.

The examiner respectfully notes that because the instant application was filed after copending Application No. 09/539,382, (filed 3/31/2000), the instant rejection is proper. The MPEP states:

1. Nonstatutory Double Patenting Rejections

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

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If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

MPEP 804 I (B) (1). Therefore the obviousness-type double patenting rejection of the instant application, filed 9/22/2000, over the claims of earlier-filed Application No. 09/539,382, filed 3/31/2000, is maintained and extended. A terminal disclaimer over Application No. 09/539,382, would overcome the instant rejection.

Conclusion

17. Claims 49 and 50 stand finally rejected for obviousness-type double patenting.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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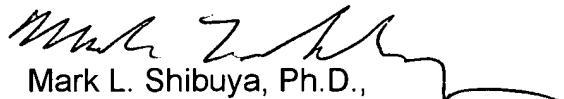
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya, Ph.D., whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Mark L. Shibuya, Ph.D.,
Primary Examiner
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